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EXAMINER	
SQUIRES, ELIZA A	
ART UNIT	**PAPER NUMBER**
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,066	DICKSON, DANE J.	
	Examiner	Art Unit	
	Eliza Squires	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15,17-27 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,17-27 and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment dated 5/6/2009 has been entered. Claims 1-13, 16, 28-29, and 38-44 have been cancelled. Claims 14, 17, 21, 26, 30, 32 and 33 have been amended. Claims 14-15, 17-27, and 30-37 are currently pending in the application.

Response to Arguments

Rejections Under 35 USC 112

2. The rejections under 35 USC 112 for the claims previously presented are withdrawn in light of the cancellation of the claims.

Rejections Under 35 USC 101

3. The rejections under 35 USC 101 are maintained.

4. Applicant argues on pages 9 and 10 that the claims meet the transformation test of *In re Abele* 684 F.2d 902 (CCPA 1982) as cited favorably in *In re Bilski* 545 F3d 943 (Fed. Cir. 2008). Specifically that processing clinical trial data into a physically different display of the data provides this transformation. *Bilski* discusses in regard to *Abele* that the "data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible". (*Bilski* p. 26) This is not the case with the instant application. The data, a clinical trial report, does not represent a physical and tangible object but merely an abstract idea, the effect of a particular

treatment. While the system of Abele transformed a physical structure into data representative of the structure, the claimed invention converts data into another form of data. Applicant argues that the data is directly related to physical attributes of human subjects (emphasis added). *Abele* more specifically requires that the end data being representative of the physical object, i.e. one could not use the output from the claimed invention to view a representation of, for example, the psychological medical conditions (a psychological medical condition is not a tangible object).

5. As to the description of an "electronic" generation of summary reports as amended into the independent claim (which may also constitute new matter); this also fails to meet the machine test cited by *Bilski*. Merely reciting "electronically generating" a report, does not describe a particular machine implementing the generating nor does it describe a particular algorithm used to generate the report.

6. It is Examiner's position that an electronic display of the report, is insignificant post solution activity. The claims therefore fail to meet both the machine and transformation test as described in *Bilski*.

Rejections Under 35 USC 102

7. The rejections under 35 USC 102 are withdrawn due to the amendments to the claims. All rejections are now found under 35 USC 103.

8. Applicant argues on pages 10-12 that *Cognigen* fails to teach a template common to other of the individual summary reports. Applicant appears to provide in the arguments a definition of a template "various information consistent from one of the summary reports to another of the summary reports". *Cognigen* meets this definition. Each of the summary reports contain a

section titled “abstract”, “objectives”, “methods”, etc. which provides information under each heading consistent in each *Cognigen* reference, i.e. both papers contain methods information, results information, etc.

9. While applicant argues that they are not in the same area on the document and are not the same length, this is not specifically claimed. During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See In re Morris, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997).

10. Applicant additionally argues that a patient characteristic region is found in *Rubino* and not *Hammel* therefore the reference does not comprise a template. Both contain the same section headings, the exact content of each section is directed toward the content of printed matter, the difference between the report of the references and the claim resides solely in the content of the printed matter, there is no functional relationship between the printed matter and the substrate (the piece of paper (substrate) or the electronic display). The claimed printed material is therefore not accorded any patentable weight. See In re Gulack, 703 F.2d 1381, 217 USPQ 401, (1983).

11. Applicant argues that in regards to claims 22 and 34 the references do not teach arm-specific information relating to at least one arm of the clinical trial. "Arm" is defined in the specification as "one or more groups into which patients are divided in a clinical trial", for example, in *Rubino* “sparse samples were obtained from patients aged… given 10mg/kg LZD every eight hours…” (abstract). The clinical trial of *Rubino* therefore has one arm and the arm specific information is at least an absorption rate (0.37/hr), number of patents (195) and LZD

concentrations available (376) (see Results section). The claimed therefore does not distinguish itself over prior art.

Response to Amendment

The amendment filed 05/06/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added limitation in claim 14 and 26 recites "electronically generating" a collection of reports.

These newly added limitations appear to constitute new matter. Applicant did not point out, nor was Examiner able to find, any support for these newly added limitations in the specification as originally filed.

Applicant is requested to clarify the issues discussed above, to specifically point out support for the newly added limitations in the originally filed specification and claims to the extent possible, and to cancel any new matter in the reply to this Office Action.

Specification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 USC 112, first paragraph for at least the same rationale as discussed above, and incorporated herein.

Claim Rejections - 35 USC § 112

Claim(s) 14 and 26 is/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As per claim(s) 14 and 26, these claims are rejected for at least the same rationale as discussed above, and incorporated herein.

NOTE:The rejection presented hereinbelow if for Applicant's consideration should Applicant properly traverses the new matter issues discussed above in the response hereto.

Claim Rejections - 35 USC § 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. **Claims 14-15, 17-27, and 30-37** are rejected under 35 U.S.C. 101. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In re Bilski et al, 88 USPQ 2d 1385 CAFC (2008); Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9

(1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the particular machine to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

Here, applicant's method steps fail the first prong of the new Federal Circuit decision since they are not tied to a machine and can be performed without the use of a particular machine.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. **Claims 14-15, 17-27, and 30-37** are rejected under 35 U.S.C. 103(a) as being anticipated by *Cognigen* Corporation posters for American Society for Clinical Pharmacology and Therapeutics meeting of April 2003 as demonstrated by "Pharmacokinetic/Pharmacodynamic analysis of data from a phase III trial of linezolid IV/PO for the treatment of resistant gram-positive bacterial infections in children" by *Rubino* et al. and "Comparison of censored regression (CR) vs standard regression (SR) analyses for modeling relationships between minimum inhibitory concentrations (MIC) and patient- and institution-specific variables" by *Hammel et al.* Hereinafter the combination of the two posters are refered to as *Cognigen,* individually the reports will be referred to by the name of the primary authors, *Rubino* and *Hammel* respectively in view of APPLICANT ADMITTED PRIOR ART.

14. Because Applicant failed to traverse the use of OFFICIAL NOTICE it is now being taken as admitted prior art. See MPEP 2144.03 C.

15. **As to claim 14,** *Cognigen* discloses a method of consistently and succinctly presenting information from multiple clinical trial reports, comprising the step of generating a collection of individual summary reports each associated with a clinical trial report of the multiple clinical trial reports, each of the individual summary reports having a template common to other of the individual summary reports, and each of the individual summary reports being prepared by:

a) displaying device bibliographical information relating to the clinical trial report in a spatially distinct, predefined bibliography region (*Cognigen* specifically see the top of the page where the title, authors, and related corporations are denoted);

b) displaying patient characteristic information relating to patients treated in a clinical trial reported in the clinical trial report in a spatially distinct, predefined patient characteristic region (*Cognigen* specifically see *Rubino* "Methods" section wherein "patients aged from birth to 11 years including term and preterm infants with suspected or proven resistant gram-positive bacterial infections…");

c) displaying end point information relating to end points of the clinical trial in a spatially distinct, predefined end point region (*Cognigen* specifically see *Rubino* "Methods" section wherein "Planned duration of therapy was to be at least 10 days with a maximum of 28 days"); and

d) displaying arm information relating to at least one arm of the clinical trial in a spatially distinct, predefined arm region (*Cognigen* specifically see *Rubino* "Results" section).

It is now APPLICANT ADMITED PRIOR ART that displaying reports via a monitor and printing reports are old and well known in the art and one of ordinary skill would immediately associate such a report as disclosed by *Cognigen* with the ability to view the report via a computer system or print via a system connected with a printer.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined *Cognigen* with APPLICANT ADMITED PRIOR for the purpose of report distribution.

16. **As to claim 15,** see the discussion of claim 14, additionally, *Cognigen* discloses the method comprising the further step of displaying a title within each spatially distinct, predefined region, said title being uniquely associated with an information type associated with and displayed in the spatially distinct region (*Cognigen* see titles "Abstract", "Introduction", "Objectives", "Methods" etc.).

17. **As to claim 17,** see the discussion of claim 14, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 16 from which this claim is dependant. Claim 16 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the substrate comprises paper since a substrate is not necessarily required.

18. **As to claim 18,** see the discussion of claims 14 and 17, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 16 from which this claim is dependant. Claim 16 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the display comprises not more than two viewable pages of paper since a substrate is not necessarily required.

19. **As to claim 19,** see the discussion of claims 14 and 17-18, additionally, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the

alternative in claim 16 from which this claim is dependant. Claim 16 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that not more than two viewable pages

of paper are disposed on opposing sides of a single sheet of paper since a substrate is not necessarily required. This is also true of claim 18 from which the claim depends since if the document was one side of printed paper it would not need to be printed on each side.

20. **As to claim 20,** see the discussion of claims 14 and 17, additionally, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 16 from which this claim is dependant. Claim 16 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the display comprises a single viewable page of paper since a substrate is not necessarily required.

21. **As to claim 21,** see the discussion of claim 14, additionally, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 16 from which this claim is dependant. Claim 16 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the display comprises a computer monitor since an electronic display device is not necessarily required.

22.

23. **As to claim 22,** see the discussion of claim 14, additionally, *Cognigen* discloses the method wherein the arm region includes information of a type selected from the group consisting of arm-specific information relating to at least one arm of the clinical trial (*Cognigen* see *Rubino* "Results" section).

24. **As to claim 23,** see the discussion of claim 14 and 22, additionally, *Cognigen* discloses the method comprising the further step of associating a visibly identifiable color with the arm region containing the arm-specific information, said visibly identifiable color being distinct from visibly identifiable colors associated with other arm-specific arm regions of the individual summary report (*Cognigen* see *Rubino* figures 1-6).

25. **As to claim 24,** see the discussion of claim 14, additionally, *Cognigen* discloses the method comprising the further step of graphically displaying information in at least one of the spatially distinct, predefined regions (*Cognigen* see *Rubino* "Results" section).

26. **As to claim 25,** see the discussion of claim 14, additionally, *Cognigen* discloses the method wherein at least one spatially distinct arm region of the display further includes an administration region containing information relating to administration of treatment during the clinical trial (*Cognigen* see *Rubino* "Methods" section).

27. **As to claim 26,** *Cognigen* teaches a method for distilling and succinctly and consistently presenting information from multiple clinical trial reports, comprising the steps of:

a) generating a collection of individual summary reports each associated with a clinical trial report of the multiple clinical trial reports, each of the individual summary reports having a template common to other of the individual summary reports (*Cognigen.* Examiner notes that

Hammel is inherently associated with a clinical trial report published in the journal "Antimicrobial Agents and Chemotherapy" under the same title);

b) culling from the multiple clinical trial reports information relating to each of a group of information types;

c) preparing each of the individual summary reports by:

i) displaying bibliographical information relating to the clinical trial report in a spatially distinct, predefined bibliography region (*Cognigen* specifically see the top of the page where the title, authors, and related corporations are denoted);

ii) displaying patient characteristic information relating to patients treated in a clinical trial reported in the clinical trial report in a spatially distinct, predefined patient characteristic region(*Cognigen* specifically see *Rubino* "Methods" section wherein "patients aged from birth to 11 years including term and preterm infants with suspected or proven resistant gram-positive bacterial infections…");

iii) displaying end point information relating to end points of the clinical trial in a spatially distinct, predefined end point region (*Cognigen* specifically see *Rubino* "Methods" section wherein "Planed duration of therapy was to be at least 10 days with a maximum of 28 days"); and

iv) displaying arm information relating to at least one arm of the clinical trial in a spatially distinct, predefined arm region (*Cognigen* specifically see *Rubino* "Results" section).

It is now APPLICANT ADMITED PRIOR ART that displaying reports via a monitor and printing reports are old and well known in the art and one of ordinary skill would

immediately associate such a report as disclosed by *Cognigen* with the ability to view the report via a computer system or print via a system connected with a printer.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined *Cognigen* with APPLICANT ADMITED PRIOR for the purpose of report distribution.

28. **As to claim 27,** see the discussion of claim 26, additionally, *Cognigen* discloses the method comprising the further step of displaying a title within each spatially distinct, predefined region, said title being uniquely associated with an information type associated with and displayed in the spatially distinct region (*Cognigen* see titles "Abstract", "Introduction", "Objectives", "Methods" etc.).

29. **As to claim 30,** see the discussion of claim 26, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 28 from which this claim is dependant. Claim 28 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the display comprises not more than two viewable pages of paper since a substrate is not necessarily required.

30. **As to claim 31,** see the discussion of claim 26 and 30, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 28 from which this claim is dependant. Claim 28 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As

such, it is not then required for prior art to demonstrate that not more than two viewable pages of paper are disposed on opposing sides of a single sheet of paper since a substrate is not necessarily required. This is also true of claim 30 from which the claim depends since if the document was one side of printed paper it would not need to be printed on each side.

31. **As to claim 32,** see the discussion of claims 26, additionally, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 28 from which this claim is dependant. Claim 28 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the display comprises a single viewable page of paper since a substrate is not necessarily required.

32. **As to claim 33,** see the discussion of claim 26, additionally, Examiner notes that each individual summary report is displayed on a display comprising a member selected from the group consisting of a substrate and an electronic display device are recited in the alternative in claim 28 from which this claim is dependant. Claim 28 merely requires that a member selected from the group must be met to fall within the scope of the claims, not that each is required. As such, it is not then required for prior art to demonstrate that the display comprises a computer monitor since an electronic display device is not necessarily required.

33. **As to claim 34,** see the discussion of claim 26, additionally, *Cognigen* discloses the method wherein the arm region includes information of a type selected from the group consisting of arm-specific information relating to at least one arm of the clinical trial (*Cognigen* see *Rubino* "Results" section).

34. **As to claim 35,** see the discussion of claims 26 and 34, additionally, *Cognigen* discloses the method comprising the further step of associating a visibly identifiable color with the arm region containing the arm-specific information, said visibly identifiable color being distinct from visibly identifiable colors associated with other arm-specific arm regions of the individual summary report (*Cognigen* see *Rubino* figures 1-6).

35. **As to claim 36,** see the discussion of claim 26, additionally, *Cognigen* discloses the method comprising the further step of graphically displaying information in at least one of the spatially distinct, predefined regions (*Cognigen* see *Rubino* "Results" section).

36. **As to claim 37,** see the discussion of claim 26, additionally, *Cognigen* discloses the method wherein at least one spatially distinct arm region of the display further includes an administration region containing information relating to administration of treatment during the clinical trial (*Cognigen* see *Rubino* "Methods" section).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./
Examiner, Art Unit 3626
6/15/2009

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626